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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,324	08/22/2001	Joan W. Conaway	OMRF 1001	3570

7590 09/23/2003

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EXAMINER
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NICKOL, GARY B

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 09/23/2003

15

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/914,324

Applicant(s)

CONAWAY ET AL.

Examiner

Gary B. Nickol Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) 2-6 and 8-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,7 and 24-33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 14.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### DETAILED ACTION

Applicant's election with traverse of Group 1, claims 1, and 7 in Paper No. 13 is acknowledged. The traversal is on the ground(s) that, at the very least, claim 1 is a "genus" claim linking the isolated Ring box protein(s) and dependent species claims drawn to "protein complexes" comprising such proteins. Essentially, it appears that applicants are arguing that Groups 3 and 4 should be included in the examination. This argument has been considered but is not found persuasive. Groups 3 and 4 are drawn to special technical features which are not so linked as to include the special technical feature of Group 1 for the reasons set forth in Paper No. 12.

However, in view of the fact that applicants have added new claims dependent from the special technical feature set forth in Claims 1 and 7, clarification of the restriction was necessary. On September 16, 2003, a telephone call was placed to Beth L. Kelly seeking clarification of species to the newly added claims. Applicants agreed to elect the following species:

Claim 28: a Cullin protein

Claim 30: SCF

Claim 31: Cullin 1

Claim 32:  $\beta$ -TRCP

Claim 33: Skp 1

Affirmation of this election must be made by applicant in replying to this Office action.

For the reason set forth above, the Restriction is made final.

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Claims 2-6 and 8-23 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claims 1, 7, and 24-33 are pending.

The elected species of "SCF" (Claim 30) in combination with the Ring Box protein is found to be free of the art. Thus, the next species of "VHL" was searched.

The elected species of "Cullin 1" (Claim 31) in combination with the Ring Box protein is found to be free of the art. Thus, the next species of "Cullin 2" was searched.

The elected species of " $\beta$ -TRCP" (Claim 32) in combination with the Ring Box protein is found to be free of the art. Thus, the next species of "VHL" was searched. (A species election between VHL and Elongin C in Claim 32 is withdrawn since art was found on both species)

The elected species of "Skp 1" (Claim 33) in combination with the Ring Box protein is found to be free of the art. Thus, the next species of "Elongin C" was searched.

### ***Claim Objections***

Claim 1 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 7. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper to object to the claims as being substantial duplicates. See MPEP § 706.03(k).

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 7, and 24-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Duan *et al.* (Proc.Natl.Acad.Sci., July 1995, Vol. 92, pages 6459-6463) as further evidenced by Pause *et al.* (Proc.Natl.Acad.Sci., March 1997, Vol. 94, pages 2156-2161).

Duan *et al.* teach an isolated and purified biologically active human protein of 16 kDa (abstract, and page 6460, 2<sup>nd</sup> column). Both the Duan *et al.* protein and SEQ ID NO:1 of the claimed invention exist as part of a VHL complex wherein the specification also teaches isolation of a 16 kDa protein (page 9, lines 9-12). Absent evidence to the contrary, this protein is the same as applicant's and is inherently a Ring box protein comprising a polypeptide having the amino acid sequence of SEQ ID NO:1 which is encoded by a nucleic acid of SEQ ID NO:3. Duan *et al.* further teach a protein complex comprising the Ring box protein wherein the complex is a ubiquitin ligase protein complex wherein the ubiquitin ligase protein is VHL. Since the prior art teaches that the complex includes VHL, this reads on the limitations of Claim 28, drawn to a substrate recognition protein which is VHL as set forth in Claim 32. Furthermore, as evidenced by Pause *et al.* (abstract), the VHL product also forms a stable complex with one or more proteins selected from the group consisting of a cullin protein (Claim 28) wherein the cullin protein is selected from the group consisting of a Cullin 2 (Claim 31). Pause *et al.* also

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teach (page 2156, 2<sup>nd</sup> column) that the VHL product is known to stably associate with the two regulatory subunits, B and C, of the trimeric transcription elongation factor, elongin. Thus, the latter teaching reads on the protein complex further comprising a linker protein (Claim 28), wherein said linker protein is Elongin C (Claim 33) and or a protein complex further comprising a substrate recognition protein (Claim 28) wherein said substrate recognition protein is Elongin C binding proteins (Claim 32).

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 703-305-7143. The examiner can normally be reached on M-F, 8:30-5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

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Gary B. Nickol, Ph.D.

Examiner

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GBN

September 17, 2003

*Gary B. Nickol*